

K190621 SB Knife/Short type, SB Knife/Standard type, SB Knife/Jr type, SB Knife/Jr type - LongApr 23, 2019
43 days to decisionK190621 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Mar 11, 2019
Decision date	Apr 23, 2019
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sumitomo Bakelite Co., Ltd.
Location	Tokyo, JP
Contact	Shiro Agehama
510(k) history	4 submissions · 4 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Mic International Corp.
Contact	Izumi Maruo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190621/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026